

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

NOVARTIS PHARMACEUTICALS
CORPORATION,

Plaintiff,

V.

MACLEODS PHARMACEUTICALS
LTD., MACLEODS PHARMA USA,
INC.,

Defendants.

C.A. No. _____

COMPLAINT

Novartis Pharmaceuticals Corporation (“Novartis”), by its attorneys, hereby alleges as follows:

NATURE OF THE ACTION

1. This is a patent infringement action arising under Title 35 of the United States Code and concerning Abbreviated New Drug Applications (“ANDAs”) submitted to the United States Food and Drug Administration (“FDA”) by the above-named defendants seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of sacubitril/valsartan tablets, generic versions of Novartis’s ENTRESTO® tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg, prior to the expiration of U.S. Patents Nos. 8,101,659 (the “659 patent”), 8,877,938 (the “938 patent”), and 9,388,134 (the “134 patent”).

2. This particular New Jersey suit is a Hatch-Waxman “backup suit,” intended to safeguard Novartis’s rights under 21 U.S.C. § 355 *et seq.* in the event of potential disputes over jurisdiction and/or venue. A substantively identical suit was filed earlier in the District of

Delaware against Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. Twelve other groups of generic drug-maker defendants thus far have been sued in Delaware in connection with their ANDAs for generic versions of Novartis's ENTRESTO[®] tablets.

PARTIES

3. Plaintiff Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business in East Hanover, New Jersey.

4. On information and belief, defendant Macleods Pharmaceuticals Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Atlanta Arcade, Marol Church Road, Andheri (East), Mumbai, India.

5. On information and belief, defendant Macleods Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 666 Plainsboro Road, Building 200, Suite 230, Plainsboro, New Jersey 08536. On information and belief, Macleods Pharma USA, Inc. is a wholly owned subsidiary of Macleods Pharmaceuticals Ltd.

6. On information and belief, Macleods Pharmaceuticals Ltd. develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including New Jersey, either directly or indirectly.

7. On information and belief, Macleods Pharma USA, Inc. develops, manufactures, distributes, sells, and/or imports drug products for the entire United States market and does business in every state including New Jersey, either directly or indirectly.

8. By a letter dated September 11, 2019 ("Macleods Notice Letter"), Macleods Pharmaceuticals Ltd. notified Novartis that (i) Macleods Pharmaceuticals Ltd. had submitted to

the FDA ANDA No. 213728 for sacubitril/valsartan tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg (“Macleods ANDA Products”), seeking FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Macleods ANDA Products in or into the United States, including New Jersey, prior to the expiration of the ’659, ’938, and ’134 patents, and that (ii) ANDA No. 213728 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the ’659, ’938, and ’134 patents.

9. Macleods Pharmaceuticals Ltd. has committed an act of infringement in this judicial district by filing ANDA No. 213728 with the intent to make, use, sell, offer for sale, and/or import the Macleods ANDA Products in or into this judicial district, prior to the expiration of the ’659, ’938, and ’134 patents, an act of infringement that has led and will lead to foreseeable harm and injury to Novartis, a corporation having a principal place of business in New Jersey.

10. On information and belief, Macleods Pharma USA, Inc. acted in concert with and under the direction of Macleods Pharmaceuticals Ltd. in the preparation and submission of ANDA No. 213728, and, if the ANDA is approved, will act in concert with under the direction of Macleods Pharmaceuticals Ltd. to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Macleods ANDA Products in or into the United States, including New Jersey, prior to the expiration of the ’659, ’938, and ’134 patents.

11. Macleods Pharmaceuticals Ltd., by itself or together with Macleods Pharma USA, Inc., has taken the costly, significant step of applying to the FDA for approval to engage in future activities, including the marketing of the Macleods ANDA Products, that will be purposefully directed at New Jersey and elsewhere.

12. On information and belief, Macleods Pharmaceuticals Ltd. has systematic and continuous contacts with New Jersey; has established distribution channels for drug products in New Jersey; regularly and continuously conducts business in New Jersey, including by selling drug products in New Jersey, either directly or indirectly through its subsidiaries, agents, or affiliates, including Macleods Pharma USA, Inc.; has purposefully availed itself of the privilege of doing business in New Jersey; and derives substantial revenue from the sale of drug products in New Jersey.

13. Macleods Pharmaceuticals Ltd. has availed itself of the legal protection of the State of New Jersey by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey. *See, e.g., Celgene Corp. v. Macleods Pharms. Ltd.*, C.A. No. 18-11212 (D.N.J.).

JURISDICTION AND VENUE

14. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

15. This Court has personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. because, on information and belief, each such Defendant has committed or has aided, abetted, contributed to, or participated in the commission of tortious acts of patent infringement in preparing and submitting ANDA No. 213728 with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which acts have led to foreseeable harm and injury to Novartis, a corporation having a principal place of business in New Jersey.

16. This Court also has personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. because, on information and belief, each such Defendant, upon approval of ANDA No. 213728, will commit or will aid, abet, contribute to, or participate in

future tortious acts of patent infringement permitted under ANDA No. 213728 that will be purposefully directed at New Jersey, including the marketing of the Macleods ANDA Products in New Jersey, prior to the expiration of the '659, '938, and '134 patents.

17. This Court also has personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. because, on information and belief, each such Defendant's affiliations with the State of New Jersey, including Macleod Pharma USA, Inc.'s having a principal place of business in New Jersey, and Macleods Pharmaceuticals Ltd.'s ownership of and actions in concert with Macleods Pharma USA, Inc., are sufficiently continuous and systematic as to render each such Defendant essentially at home in this forum.

18. This Court also has personal jurisdiction over Macleods Pharmaceuticals Ltd. because Macleods Pharmaceuticals Ltd. has availed itself of the legal protections of the State of New Jersey, by admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey.

19. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc.

20. Venue is proper in this Court because Macleods Pharma USA, Inc. has committed and/or will commit acts of infringement in this judicial district and has a regular and established place of business in this judicial district, and because Macleods Pharmaceuticals Ltd. is a foreign entity who may be sued in any judicial district, including New Jersey. 28 U.S.C. § 1400(b); 28 U.S.C. § 1391(c)(3).

THE PATENTS-IN-SUIT AND ENTRESTO®

21. Novartis is the owner of the '659 patent, titled "Methods of treatment and pharmaceutical composition." The '659 patent was duly and legally issued on January 24, 2012. A true and correct copy of the '659 patent is attached hereto as Exhibit A.

22. The '659 patent claims, *inter alia*, a pharmaceutical composition comprising (i) valsartan or a pharmaceutically acceptable salt thereof; (ii) sacubitril or sacubitrilat or a pharmaceutically acceptable salt thereof; and (iii) a pharmaceutically acceptable carrier; wherein (i) and (ii) are administered in combination in about a 1:1 ratio.

23. Novartis is the owner of the '938 patent, titled "Compounds containing S-N-valeryl-N- {[2'-(1H-tetrazole-5-yl)-biphenyl-4-yl]-methyl}-valine and (2R,4S)-5-biphenyl-4-yl-4-(3-carboxy-propionylamino)-2-methyl-pentanoic acid ethyl ester moieties and cations." The '938 patent was duly and legally issued on November 4, 2014. A true and correct copy of the '938 patent is attached hereto as Exhibit B.

24. The '938 patent claims, *inter alia*, trisodium [3-((1S,3R)-1-biphenyl-4-ylmethyl-3-ethoxycarbonyl-1-butylcarbamoyl)propionate-(S)-3'-methyl-2'-(pentanoyl {2''-(tetrazol-5-ylate)biphenyl-4'-ylmethyl} amino)butyrate] hemipentahydrate ("sacubitril/valsartan trisodium hemipentahydrate complex") in crystalline form.

25. Novartis is the owner of the '134 patent, titled "Compounds containing S-N-valeryl-N- {[2'-(1H-tetrazole-5-yl)-biphenyl-4-yl]-methyl}-valine and (2R,4S)-5-biphenyl-4-yl-4-(3-carboxy-propionylamino)-2-methyl-pentanoic acid ethyl ester moieties and cations." The '134 patent was duly and legally issued on July 12, 2016. A true and correct copy of the '134 patent is attached hereto as Exhibit C.

26. The '134 patent claims, *inter alia*, a method for the treatment of heart failure or hypertension, in a patient in need thereof comprising administering to the patient a therapeutically effective amount of a sacubitril/valsartan trisodium hemipentahydrate complex.

27. Novartis is the holder of New Drug Application (“NDA”) No. 207620 by which the FDA granted approval for the commercial manufacturing, marketing, sale, and use of ENTRESTO[®] (sacubitril and valsartan) tablets, 24 mg/26 mg, 49 mg/51 mg, and 97 mg/103 mg. ENTRESTO[®] currently is indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction, and for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in pediatric patients aged one year and older.

28. One or more claims of each of the '659, '938, and '134 patents cover ENTRESTO[®] and/or the use thereof.

29. The FDA's official publication of approved drugs (the “Orange Book”) lists the '659, '938, and '134 patents in connection with ENTRESTO[®].

INFRINGEMENT OF THE PATENTS-IN-SUIT

30. Novartis incorporates paragraphs 1 – 13 and 21 – 29 as if fully set forth herein.

31. On information and belief, Macleods Pharmaceuticals Ltd., by itself or in concert with Macleods Pharma USA, Inc., submitted to the FDA ANDA No. 213728 under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Macleods ANDA Products prior to the expiration of the '659, '938, and '134 patents.

32. This action was commenced within 45 days of Novartis's receipt of the Macleods Notice Letter.

33. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Macleods ANDA Products in or into the United States prior to the expiration of the '659, '938, and '134 patents, Macleods Pharmaceuticals Ltd., and, on information and belief, Macleods Pharma USA, Inc., have committed an act of infringement under 35 U.S.C. § 271(e)(2).

34. On information and belief, when Macleods Pharmaceuticals Ltd. filed ANDA No. 213728, Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. were aware of the '659, '938, and '134 patents and that the filing of the ANDA with the request for its approval prior to the expiration of the '659, '938, and '134 patents was an act of infringement of those patents.

35. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Macleods ANDA Products in or into the United States will infringe one or more claims of the '659, '938, and '134 patents.

36. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Macleods ANDA Products in or into the United States will directly infringe one or more claims of the '659 patent.

37. On information and belief, the commercial manufacture, use, sale, offer for sale, and/or importation of the Macleods ANDA Products in or into the United States will directly infringe one more claims of the '938 patent.

38. On information and belief, the Macleods ANDA Products, if approved, will contain instructions for practicing a method for the treatment of heart failure in a patient in need thereof comprising administering to the patient a therapeutically effective amount of a

sacubitril/valsartan trisodium hemipentahydrate complex, which administration will constitute direct infringement of one or more claims of the '134 patent. On information and belief, if the Macleods ANDA Products are approved, physicians and/or patients following said instructions will directly infringe one or more claims of the '134 patent. On information and belief, if the Macleods ANDA Products are approved, Macleods Pharmaceuticals Ltd. and/or Macleods Pharma USA, Inc. will actively encourage, recommend, or promote this infringement with knowledge of the '134 patent, and with knowledge and intent that their acts will induce infringement of one or more claims of the '134 patent.

39. On information and belief, if the Macleods ANDA Products are approved, Macleods Pharmaceuticals Ltd. and/or Macleods Pharma USA, Inc. will commercially manufacture, sell, offer for sale, and/or import those products, which will be specifically labeled for use in a method for the treatment of heart failure in a patient in need thereof comprising administering to the patient a therapeutically effective amount of a sacubitril/valsartan trisodium hemipentahydrate complex, as recited in one or more claims of the '134 patent. On information and belief, if the Macleods ANDA Products are approved, those products will constitute a material part of a method for the treatment of heart failure in a patient in need thereof comprising administering to the patient a therapeutically effective amount of a sacubitril/valsartan trisodium hemipentahydrate complex, as recited in one or more claims of the '134 patent. On information and belief, if the Macleods ANDA Products are approved, physicians and/or patients following the instructions in the Macleods ANDA Products will directly infringe one or more claims of the '134 patent. On information and belief, if the Macleods ANDA Products are approved, Macleods Pharmaceuticals Ltd. and/or Macleods Pharma USA, Inc. will contributorily infringe one or more claims of the '134 patent, and will do so with knowledge of the '134 patent, and that

the Macleods ANDA Products are especially made or especially adapted for use in infringing one or more claims of the '134 patent and are not suitable for a substantial noninfringing use.

40. Novartis will be substantially and irreparably damaged by Macleods Pharmaceuticals Ltd.'s and/or Macleods Pharma USA, Inc.'s infringement of the '659, '938, and '134 patents.

41. Novartis is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of ANDA No. 213728 be a date that is no earlier than July 14, 2023, the expiration of the '659 patent's pediatric exclusivity, November 27, 2027, the expiration date of the '938 patent's pediatric exclusivity, and May 8, 2027, the expiration of the '134 patent's pediatric exclusivity, or a date no earlier than the expiry of any other patent extension or exclusivity to which Novartis is entitled, and an award of damages for any commercial sale or use of the Macleods ANDA Products and any act committed by Macleods Pharmaceuticals Ltd. and/or Macleods Pharma USA, Inc. with respect to the subject matter claimed in the '659, '938, and '134 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

42. On information and belief, Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. have taken and continue to take active steps towards the commercial manufacture, use, sale, offer for sale, and/or importation of the Macleods ANDA Products, including seeking approval of those products under ANDA No. 213728.

43. There is a substantial and immediate controversy between Novartis and Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. concerning the '659, '938, and '134 patents. Novartis is entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. will infringe, induce

infringement of, and/or contributorily infringe one or more claims of the '659, '938, and '134 patents.

PRAYER FOR RELIEF

WHEREFORE, Novartis prays that this Court grant the following relief:

44. Judgment that defendants Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. have infringed one or more claims of the '659, '938, and '134 patents by filing ANDA No. 213728;

45. A permanent injunction restraining and enjoining defendants Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc., and their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, sale, or offer for sale in the United States, or importation into the United States, of the Macleods ANDA Products prior to the expiration of the '659, '938, and '134 patents, inclusive of any extensions and additional periods of exclusivity;

46. An order that the effective date of any approval of ANDA No. 213728 be a date that is not earlier than the expiration dates of the '659, '938, and '134 patents, inclusive of any extensions and additional periods of exclusivity;

47. Declaratory judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of the Macleods ANDA Products will directly infringe, induce infringement of, and/or contributorily infringe one or more claims of the '659, '938, and '134 patents;

48. Damages or other monetary relief from defendants Macleods Pharmaceuticals Ltd. and Macleods Pharma USA, Inc. for the infringement, inducement of infringement and contributory infringement of the '659, '938, and '134 patents;

49. A declaration that this case is an exceptional case pursuant to 35 U.S.C. § 285 and an award of attorney's fees;

50. Novartis's costs and expenses in this action; and

51. Such other and further relief as the Court may deem just and proper.

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Rule 11.2, I hereby certify that the matter in controversy is the subject of the following action involving the same parties and the same patents-in-suit:

NOVARTIS PHARMACEUTICALS CORPORATION v. ALEMBIC
PHARMACEUTICALS LIMITED, et al., C.A. No. 19-cv-2021 (D. Del.)

In addition, the following action involves different defendants, and at least one of the same patents-in-suit:

NOVARTIS PHARMACEUTICALS CORPORATION v. ALKEM LABORATORIES
LTD., et al., C.A. No. 1:19-cv-01979 (LPS) (D. Del.)

Dated: October 25, 2019

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